DEPARTMENT OF HEALTH & HUMAN SERVICES
Food and Drug Administration
New England District

HFI-35

5153

One Montvale Avenue
Stoneham, Massachusetts 02180
(781) 279-1675
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Febuary 01, 2001

WARNING LETTER

NWE–12–01W

VIA FEDERAL EXPRESS

David C. Footit, Owner
D&K Farm
81 School Street
Middlefield, CT 06455

Dear Mr. Footit:

An inspection of your dairy operation located in Wallingford, CT (D&K Farm, 180 Northford Road) was conducted by Investigator John Hollings on December 12 and 18, 2001. That inspection confirmed that you offered an animal for sale for slaughter as food in violation of Sections 402(a)(2)(C)(ii) and 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act), and that you may have caused animal drugs to become adulterated within the meaning of Section 501(a)(5) of the Act.

In November 2000, you sold (traded) a dairy cow identified with farm tag 34 and back tag [redacted], for slaughter as human food to [redacted], a livestock dealer in [redacted] CT. This animal was shipped to the [redacted] Packing Co., [redacted], PA where it was slaughtered. USDA analysis of tissue samples collected from that animal identified the presence of gentamicin in the animal's kidney at a level of 4.74 ppm. Gentamicin has not been approved for use in cattle. There is no established tolerance for residues of gentamicin in the edible tissues of cattle. The presence of this drug in edible tissue from this animal causes the food to be adulterated.

Our investigation also found that you hold animals under conditions which are so inadequate that diseased animals and/or medicated animals bearing potentially harmful drug residues are likely to enter the food supply. For example, you lack an adequate system for assuring that animals have been treated only with drugs that have been approved for use in those species; for assuring that drugs are used in a manner not

contrary to the directions contained in the labeling; and for assuring that animals medicated by you have been withheld from slaughter for appropriate periods of time to permit depletion of potentially hazardous residues of drugs from edible tissues. Food from animals held under such conditions are adulterated.

You are adulterating the drug [redacted] brand of Gentamicin Sulfate Solution (Veterinary) that your firm uses on dairy cattle within the meaning of Section 501(a)(5) of the Act, when you fail to use the drug in conformance with the approved conditions of use. Gentamicin is not approved for use in dairy cattle. Use of this drug contrary to the approved conditions of use may only be done when a veterinarian is involved in the decision based on a valid veterinarian / client / patient relationship, no residue occurs, and other conditions, described in Title 21, Code of federal Regulations, Part 530, have been met.

This letter is not intended to be an all-inclusive list of violations. As a producer of animals that are offered for use as food, you are responsible for assuring that your overall operation and the food you distribute are in compliance with the law.

You should take prompt action to correct these violations and to establish procedures to prevent their recurrence. Failure to promptly correct these violations may result in regulatory action without further notice, such as seizure and/or injunction.

It is not necessary for you to personally ship an adulterated animal in interstate commerce to be responsible for a violation of the Federal Food, Drug, and Cosmetic Act. The fact that you caused the adulteration of an animal that was sold and subsequently offered for sale to a slaughterhouse that ships in interstate commerce is sufficient to hold you responsible for a violation of the Act.

You should notify this office in writing within fifteen (15) working days of the steps you have taken to bring your firm into compliance with the law. Your response should include each step being taken, that has been taken, or will be taken to correct the violations and prevent their recurrence. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time frame within which the corrections will be completed. Please include copies of any available documentation demonstrating that corrections been made.

Your reply should be directed to Mark Lookabaugh, Compliance Officer at the address noted above. If you have any questions concerning this matter, please contact Mr. Lookabaugh at ***781.279.1675 x1718***,

Sincerely,

Gail T. Costello
Director
New England District Office